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EXAMINER

MILLER, CHERYL L

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 09/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/931,692

Applicant(s)

JIM MCGHAN

Examiner

Cheryl L. Miller

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 August 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Information Disclosure Statement*

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

### *Specification*

2. The disclosure is objected to because of the following informalities: In the section Brief Description of the Drawing, no description of fig. 10 is present.

Appropriate correction is required.

### *Claim Objections*

3. Claim 10 is objected to because of the following informalities: A spelling error is present in line 4. It is suggested to change "comsisting" to recite --consisting--. Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 12 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. An antibiotic is not disclosed in the specification or shown in the drawing as being "disposed between said core portion and said bioabsorbable portion".

*Claim Rejections - 35 USC § 102*

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

7. Claims 1-2, 5-6, 10, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Berman (USPN 6,017,366). Berman discloses a hybrid medical implant, which includes all limitations recited in the claims. See figure 3, 7, and respective portions of the specification. Berman discloses an implant (41) comprising an elastomeric, nonbioabsorbable core portion (81) having an outer surface and a bioabsorbable portion (83) affixed to the outer surface. Berman discloses an implant (41) having an outer surface with irregular topography (col.6, lines 1-5). Berman discloses a core portion comprising a solid elastomeric body (fig.7; col.6, lines 61-63). Berman discloses a bioabsorbable portion comprising collagen, chitin, chitosan, polymers or copolymers of lactide, glycolide, caprolactone, polydioxanone, trimethylene carbonate, polyorthoesters or polyethylene oxide (col.6, lines 22-31), wherein the bioabsorbable portion comprises a plurality of bioabsorbable materials (col.6, lines 33-36).

8. Claims 1-6 and 10-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Corbitt, Jr. et al. (USPN 6,214,045 B1). Corbitt discloses a hybrid medical implant, which includes all limitations recited in the claims. See figures 4-6 and respective portions of the specification. Corbitt discloses an implant (10, 20) comprising an elastomeric, nonbioabsorbable core portion (14) having an outer surface and a bioabsorbable portion (12) affixed to the outer surface. Corbitt discloses an implant (10, 20) having

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an outer surface with irregular topography (col.2, lines 53-54; col.3, lines 17-21, 45-49, 54-55). Corbitt discloses a core comprising a fluid filled shell ((18); col.3, lines 7-9). Corbitt discloses a core portion comprising a solid elastomeric body (col.3, lines 54-55). Corbitt discloses a bioabsorbable portion comprising collagen, chitin, chitosan, polymers or copolymers of lactide, glycolide, carpolactone, polydioxanone, trimethylene carbonate, polyorthoesters or polyethylene oxide (col.4, lines 6-13), wherein the bioabsorbable portion comprises a plurality of bioabsorbable materials (col.4, lines 17-19). Corbitt discloses bioabsorbable materials comprising antibiotics (col.4, lines 31-34).

9. Claims 1, 3, 5, 7, 9, 10, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Naficy (USPN 4,298,998). Naficy discloses a hybrid medical implant, which includes all limitations recited in the claims. See figures 5-10 and respective portions of the specification. Naficy discloses an implant (12) comprising an elastomeric, nonbioabsorbable core portion (13) having an outer surface and a bioabsorbable portion (16) affixed to the outer surface. Naficy discloses a core (13) comprising a fluid filled shell (14), (col.8, lines 49-51). Naficy discloses a core portion (13) comprising a solid elastomeric body (15, 25), (col.7, lines 1-5; col.9, lines 30-32). Naficy discloses a core (13) or shell (14) comprising silicone (col.3, lines 49-52). Naficy discloses a bioabsorbable portion comprising collagen, chitin, chitosan, polymers or copolymers of lactide, glycolide, carpolactone, polydioxanone, trimethylene carbonate, polyorthoesters or polyethylene oxide (col.7, lines 63-68), wherein the bioabsorbable portion comprises a plurality of bioabsorbable materials (16, 17).

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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11. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Berman (USPN 6,017,366) in view of Naficy (USPN 4,298,998). Berman discloses a hybrid medical implant comprising a nonbioabsorbable core portion substantially as claimed and described in above rejection. Berman does not disclose however a silicone core portion. Naficy teaches a hybrid medical implant having a nonbioabsorbable core portion made of silicone as the nonbioabsorbable core in order to provide malleability and compatibility (col.3, lines 49-53; col.5, lines 49-54). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Naficy's teaching of nonbioabsorbable silicone core, with Berman's nonbioabsorbable core medical implant to provide a permanent malleable medical implant.

*Conclusion*

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl L. Miller whose telephone number is (703) 305-2812. The examiner can normally be reached on Monday through Friday from 7:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Cheryl Miller

September 6, 2002



BRUCE SNOW  
PRIMARY EXAMINER